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EXAMINER	
SCHWADRON, R	
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Please find
pro[illegible] below and/or attached an Office communication concerning this application or [illegible]ding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/164,233	Applicant(s) Gaiger et al.
Examiner Ron Schwadron, Ph.D.	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on 2/6/2001

2a) [ ] This action is **FINAL.** 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) 10, 23-112 is/are pending in the application.

4a) Of the above, claim(s) 10, 23-103, 105, 106 is/are withdrawn from consideratio

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) 104, 107-112 is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are objected to by the Examiner.

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____.
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) [X] Notice of References Cited (PTO-892)

16) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) [X] Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) [ ] Interview Summary (PTO-413) Paper No(s). _____

19) [ ] Notice of Informal Patent Application (PTO-152)

20) [ ] Other:

1. Applicant's election with traverse of Group I, claims 1-9,11-22 and the species peptide of SEQ. ID. no. 2 in Paper No. 16 is acknowledged. The traversal is on the ground(s) that are stated in said paper. This is not found persuasive because of the following reasons. Regarding applicants comments, the different WT1 derived peptides have different amino acid sequences and would require different searches over the prior art. The requirement is still deemed proper and is therefore made FINAL.

2. Claims 10, 23-103,105,106 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction/election) in paper No. 16. Regarding claim 106, said claim is drawn to a nonelected invention (eg. a mimetic (Group II in the restriction requirement enunciated in the previous Office Action). Regarding claim 105, said claim is drawn to a nonelected species (eg. a peptide that differs from SEQ. ID. no. 2).

3. Claims 104,107-112 are under consideration.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any
> person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 104, 107-112 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the peptide of claim 104. Original claim 1 discloses a similar peptide, but also includes the limitation that the peptide comprises no more than 16 consecutive amino acids from a native WT1 polypeptide. The peptide of claim 104 does not include said limitation. Original claim 8 also differs in scope from claim 104 (eg. it comprises two different peptides with specific

limitations as per recited in said claim).
The peptide disclosed in original claim 21 differs from the peptide of claim 104 in that the peptide recited in claim 21 does not include the limitation "react with the WT1-specific antisera". Regarding applicants comments about the specification, pages 44 and 97, said pages of the specification do not disclose the scope of the claimed invention (eg. they refer to the peptide of SEQ. ID. no. 2, without disclosing the other limitations recited in claim 104). There is no support in the specification as originally filed for the scope of the claimed invention (eg. the claimed invention constitutes new matter).

There is no support in the specification as originally filed for the recitation of "immunogenic composition" in claims 108-112. While the specification discloses vaccines with the properties recited in claims 108-112, there is no disclosure of immunogenic compositions in the specification as originally filed. These two terms differ in scope in that the art recognizes that a vaccine is used for treatment of disease, including human disease, while an immunogenic composition has art recognized uses other than treating disease (eg. for making antibodies, etc.). There is no support in the specification as originally filed for the scope of the claimed invention (eg. the claimed invention constitutes new matter).

6. Claims 66-68,70,71,73 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed peptides.

The instant claims encompass a variant peptide wherein said peptide encodes an immunogenic peptide wherein said peptide binds MHC of an animal (eg. T cell binding requires MHC binding of the peptide). The claims encompass a variant peptide wherein

said peptide encodes an immunogenic peptide wherein said peptide binds antisera against WT1. There are thousands of different mammals that express structurally differing MHC molecules that bind different, largely nonoverlapping sets of peptides and the specification provides written description of variants only derived from mouse or human. In addition, regarding claims that encompass immunogenic peptides which bind human MHC, the art recognizes that there are hundreds of different allotypes of MHC molecules found in humans, wherein each allotype binds a unique set of peptides not bound by a different allotype. Similarly, the specification provides written description of particular peptides that bind WT1 antisera. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. In the instant case, the specification has disclosed specific immunogenic peptides which bind MHC or WT1 antisera, while claiming peptides which bind any MHC or antisera against WT1 from any mammal. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: <u>The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention.</u> See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the

invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

7. Claims 107 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not disclose how to use the instant invention for the treatment of cancer in vivo in humans. The specification discloses that the claimed pharmaceutical composition is used for the treatment of cancer in humans. The specification has not enabled the breadth of the claimed invention in view of the teachings of the specification because the claims encompass a pharmaceutical composition for the treatment of cancer in vivo in humans. The state of the art is such that is unpredictable in the absence of appropriate evidence whether the claimed compositions can be used for treatment of cancer in vivo in humans. The specification discloses no working examples with regards to the use of the instant invention for the treatment of disease in vivo in humans.

Regarding the in vivo mouse data disclosed in the specification, Boon teaches that it is unclear whether tumor derived peptides can be used to treat human cancer. Boon discloses that a variety of potential problems exist that could prevent therapeutic application of tumor peptide vaccines in humans (eg. loss of tumor antigens and/or MHC expression by variant tumors in vivo can result in tumors which are refractory to killing by cytotoxic cells (see page 178, second column, second paragraph)). Furthermore, the aforementioned tumor antigens already occur in patients, yet are insufficient to render an antitumor response in vivo.

Undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification. See In re Wands 8 USPQ2d

1400(CAFC 1988).

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 104,107 are rejected under 35 U.S.C. 102(b) as being anticipated by Herlyn et al. (WO 95/29995).

Herlyn et al. teach a peptide comprising SEQ. ID No:2 (eg. see page 19, last paragraph wherein SEQ. ID. No:2 is found in amino acids 1-181 of human WT1), wherein said peptide is immunogenic (eg. it induces antibodies, see page 20). The pharmaceutically acceptable excipient is the buffer that said peptide is dissolved in (see page 20, example 2).

10. Claims 104,107,108 are rejected under 35 U.S.C. 102(e) or 102(a) as being anticipated by Call et al. (US Patent 5,726,288).

Call et al. teach an immunogenic peptide comprising SEQ. ID No:2 (eg. see column 16, wherein polypeptide refers to WT1), wherein said peptide is in a pharmaceutically acceptable excipient (eg. it is to be used therapeutically, see column 16, penultimate paragraph, first sentence). Call et al. teach peptides encompassed by the "variant" recited in claim 104 wherein said variants are used with a non-specific immune response enhancer(see Example 4).

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 104,107-112 are rejected under 35 U.S.C. 103(a) as obvious over Herlyn et al. (WO 95/29995) or Call et al. (US Patent 5,726,288) in view of Jager et al. (US Patent 6,093,313).

Herlyn et al. teach a peptide comprising SEQ. ID No:2 (eg. see page 19, last paragraph wherein SEQ. ID. No:2 is found in amino acids 1-181 of human WT1), wherein said peptide is immunogenic (eg. it induces antibodies, see page 20). The pharmaceutically acceptable excipient is the buffer that said peptide is dissolved in (see page 20, example 2). Call et al. teach an immunogenic peptide comprising SEQ. ID No:2 (eg. see column 16, wherein polypeptide refers to WT1), wherein said peptide is in a pharmaceutically acceptable excipient (eg. it is to be used therapeutically, see column 16, penultimate paragraph. first sentence). Call et al. teach peptides encompassed by the "variant" recited in claim 104 (see Example 4). Neither reference teaches the peptide of composition of claim 10 using GM-CSF. Jager et al. teach use of GM-CSF as an adjuvant and compositions containing GM-CSF and a peptide (see column 6, second paragraph and column 1, first paragraph and claim 1). Jager et al. teach that GM-CSF can enhance the immune response against an antigen (see column 6, second paragraph). GM-CSF enhances a T cell response in a patient (eg. see example 4). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed inventions because Herlyn et al. or Call et al. teach the peptides recited in the claims while Jager et al. teach use of GM-CSF as an adjuvant and that GM-CSF can enhance the immune response against an antigen. One of ordinary skill in the art would have been motivated to do the aforementioned because Jager et al. teach that GM-CSF can enhance the immune response against an antigen (column 6, second paragraph). Thus, using said composition, a routineer would have achieve superior results when immunizing animals to produce antibodies as per Herlyn et al. or Call et al.

13. No claim is allowed.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644
April 22, 2001

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